

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P O. Box 1450 Alexandria, Virginsa 22313-1450 www.saylo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/224,781	01/04/1999	BARRY M. LIBIN	1059-007	3261	
JAMES V COSTIGAN HEDMAN GIBSON & COSTIGAN			EXAM	EXAMINER	
			SIMMONS, CHRIS E		
	.185 AVENUE OF THE AMERICAS NEW YORK, NY 10036		ART UNIT	PAPER NUMBER	
			1612		
			MAIL DATE	DELIVERY MODE	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BARRY M. LIBIN

Appeal 2008-2034 Application 09/224,781 Technology Center 3700

Decided: May 30, 2008

Before, TONI R. SCHEINER, DEMETRA J. MILLS, and ERIC GRIMES, *Administrative Patent Judges*.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

The following claims are representative.

- 23. A method of treating fungal infections, said method comprising contacting fungal disease sites with an amount of a composition which consists essentially of triclosan which is effective to alleviate the symptoms of said fungal infection.
- 24. A method of treating fungal infections as defined in claim 23 wherein the triclosan is combined in a liquid formulation with a solubilizer.
- 25. A method of treating fungal infections as defined in claim 23 wherein the triclosan is in a semi-solid formulation.
- 26. A method of treating fungal infections said method comprising contacting fungal disease sites with an amount of a composition which comprises triclosan and a cationic antimicrobial agent in amounts which are effective to alleviate the symptoms of said fungal infections.

References Cited by the Examiner:

Libin	5,236,699	Aug. 17, 1993
Takaoka	GB 2160099	Dec. 18, 1985
Forward	EP 0670711 B1	Feb. 17, 1999

Grounds of Rejection

- Claims 23-25 stand rejected under 35 U.S.C. § 102(b), as anticipated by Forward.
- 2. Claims 23-25 stand rejected under 35 U.S.C. § 102(b), as anticipated by Takaoka.
- 3. Claims 23-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Libin in view of Forward.

DISCUSSION

Background

"The present invention comprises a method for the prevention or treatment of mucositis, herpetic infections and fungal infections which comprises applying to the affected area an effective amount of a composition which comprises triclosan alone or in combination with a cationic antimicrobial compound." (Spec. 4.) Fungal infections treated "may include fungal infections of the head (tinea capitis), body infections (tinea corporis), 'athletes foot' (tinea pedis) as well as groin and buttocks infections (tinea crusis). The composite has also been found to be effective against superficial candidiasis (moniliasis) and cutaneous candidiasis." (Spec. 3.)

 Claims 23-25 stand rejected under 35 U.S.C. § 102(b), as anticipated by Forward.

Claim interpretation

"A determination of anticipation ... involves two steps. First is construing the claim, ... followed by a comparison of the construed claim to the prior art. This comparison process involves fact-finding, and is for the fact-finder in the first instance." *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998). Accordingly, our analysis begins by construing the claimed invention, followed by a comparison of the construed claim to the prior art.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not *materially* affect the *basic* and *novel* characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976).

However, absent a clear indication in the Specification or claims of what the basic and novel characteristics of the claimed composition actually are, the term "consisting essentially of" is construed as equivalent to "comprising." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Appellant has not defined in the Specification the scope of the invention proscribed by the claim term "consisting essentially of."

Therefore, we construe the term "consisting essentially of' in the claims as equivalent to the term "comprising." The use of the transitional phrase "comprising" itself indicates that the elements or steps following the transition may be supplemented by additional elements or steps and still fall within the scope of the claim. Scanner Technologies Corp. v. ICOS Vision Systems Corp., 365 F.3d 1299, 1303 (Fed. Cir. 2004). Thus, the methods of claims 23-25 include contacting fungal disease sites with a composition including triclosan, which may include other additional ingredients. In view of the above, we address the prior art rejections before us.

According to the Examiner, Forward discloses the treatment of fungal infections, including oral *Candida*, with a combination of triclosan and nisin. (Ans. 3.) The compositions may be in mouthwash (liquid) or gel (semisolid) form. (Ans. 3.)

Appellant contends that the

rejection is in error because the cited reference requires the presence of additional active materials that are excluded by the terms of claims 23-25. The amended claims, which include the recitation 'consisting essentially of', exclude the use of the polypeptide antibiotic nisin which is an essential component of the '711 compositions. ...

... Nisin is a polypeptide antibiotic according to the '711 [Forward] patent and therefore would have a profound and material effect on the properties of the compositions of the '711 [Forward] patent. The phrase 'consisting essentially of,' when used with triclosan, excludes other active materials because the specification and claims clearly contemplate the use of triclosan alone as the sole antifungal agent. Pages 9-11 of the original specification disclosed a number of compositions with triclosan as the sole active ingredient.

(Br. 3-4.)

The Examiner responds that "there is no evidence of record to support appellant's allegation that nisin has a 'profound and material effect on the properties' on the prior art compositions." (Ans. 6.)

Notwithstanding the Examiner's response to Appellant's arguments, this case is one which turns primarily on claim interpretation. As discussed herein, Appellant has not defined in the Specification the scope of the invention proscribed by the claim term "consisting essentially of."

Therefore, we construe the term "consisting essentially of" in claim 23 as equivalent to the term "comprising." As such, claim 23 does not exclude contacting fungal diseases with a composition comprising triclosan and other ingredients, such as nisin. Further, we agree with the Examiner that there is no evidence of record showing that nisin has a material effect on triclosan. Thus, we find that Forward anticipates claim 23.

We remind Appellant that it is his burden to precisely define the invention, not the PTO's. *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997). Appellant always has the opportunity to amend the claims during prosecution, and broad interpretation by the Examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05 (CCPA 1969).

Appellant contends that claim 24 is not anticipated by Forward because it does not disclose the use of a solubilizer. (Br. 4). However, the Examiner finds that Forward uses water alone (working examples 1-8) or in combination with ethanol (working examples 9-13 and 16) as a solvent (solubilizer), and that the surfactants disclosed by Forward at page 3, lines 15-29 would have a solubilizing function as well. (Ans. 7.) We agree with the Examiner that Forward discloses the use of a solubilizer and find claim 24 anticipated by Forward.

Appellant also argues that claim 25 is not anticipated by Forward because that patent does not disclose a semi-solid composition. (Br. 4.) The Examiner finds that the gels disclosed at page 1, lines 53, and the toothpastes prepared in working examples 1-8, of Forward are semisolids. (Ans. 7.) We agree with this finding of the Examiner and thus conclude claim 25 is anticipated by Forward.

The anticipation rejection of claims 23-25 based on Forward is affirmed

2. Claims 23-25 stand rejected under 35 U.S.C. § 102(b), as anticipated by Takaoka. We select claim 23 as representative of the

Appeal 2008-2034 Application 09/224,781

rejection before us since Appellant has not separately argued the individual claims. 37 C.F.R. 41.37(c)(1)(vii).

The Examiner contends that Takaoka "discloses the use of triclosan, either in solution with alcohol or water, or as an ointment, to treat athlete's foot fungus (see page 1, lines 35-38)." (Ans. 4.)

Appellant contends that all of the disclosed compositions employ urea as well as triclosan, and that the claim language "consisting essentially of" excludes the presence of urea. (Br. 5.)

Again we are not persuaded by Appellant's arguments in view of the claim interpretation discussed herein.

Therefore, we construe the term "consisting essentially of" in claim 23 as equivalent to the term "comprising." As such, claim 23 does not exclude contacting fungal disease sites with a composition comprising triclosan and other ingredients, such as urea. Thus we find that Takaoka anticipates claim 23, and the rejection is affirmed.

3. Claims 23-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Libin in view of Forward. We select claims 23 and 26 as representative of the rejection before us since Appellant has not separately argued the other individual claims. 37 C.F.R. 41.37(c)(1)(vii).

The Examiner finds that Libin

discloses mouthrinses comprising a combination of triclosan and cetylpyridinium chloride, which are used to inhibit plaque formation and to treat periodontitis (column 4, lines 57-60). It

¹ We note that arguments presented on page 6 of the Brief relate to the Forward reference not the Takaoka reference, and therefore, we do not address them in the rejection over Takaoka.

differs from the instant claims in its silence regarding the treatment of fungal infections.

Triclosan and cetylpyridinium chloride are both known to be active against the oral fungus *Candida*. See [Forward]. ... The reference also recognizes that these agents are equally useful for inhibiting plaque (paragraph 0043). It differs from the instant claims insofar as it does not specify the use of the two agents together.

(Ans. 4.) See, e.g. pending claims 26-28.

The Examiner concludes that

[i]t would have been obvious to have administered mouthrinses comprising triclosan and cetylpyridinium chloride to oral *Candida* patients, motivated by the desire to inhibit plaque as taught by the primary reference, while simultaneously treating the *Candida* infection as taught by the secondary reference.

(Ans. 5.)

Appellant puts forth the same arguments with respect to Forward discussed above, namely that the claims exclude the use of nisin. (Br. 7.) Appellant also argues that Libin does not explicitly mention or suggest the treatment of a fungal disease. (Br. 7.)

We are not persuaded by Appellant's arguments. We have found herein that claim 23, as interpreted, does not exclude ingredients such as nisin. Furthermore, while Libin does not explicitly disclose the use of triclosan for the treatment of fungal disease, Forward discloses that an oral hygiene composition comprising triclosan, as in Libin, is useful for the treatment of fungal infections. (Forward, p. 2. ¶ 008.) Thus, a person of ordinary skill in the art would have recognized that the Libin composition

including triclosan, would also useful for the treatment of fungal infections in view of the disclosure of Forward. (Ans. 9-10.)

Appellant also argues that claim 26 is not obvious in view of the cited references. (Br. 7.) When determining whether a claim is obvious, an examiner must make "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." In re Ochiai, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." CFMT, Inc. v. Yieldup Intern. Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing In re Royka, 490 F.2d 981, 985 (CCPA 1974)).

Libin discloses the use of triclosan in combination with a cationic agent such as cetyl pyridinium choloride in a mouthrinse, as claimed. (Libin, abstract.) Forward discloses mouthwashes for the treatment of oral fungal infections including cetyl pyridinium chloride or triclosan. (Forward, p. 2. ¶ 008.) In view of the above, we find the Examiner has provided sufficient evidence in the prior art of each of the claimed limitations and an adequate reason to combine the teachings of the prior art mouthrinses. As discussed herein, we do not find the pending claims exclude the inclusion of a nisin compound. In view of the above, the obviousness rejection is affirmed.

SUMMARY

The rejections of the claims for anticipation and obviousness are affirmed

No time period for any subsequent action in connection with this appeal may be extended under CFR § 1.136(a).

AFFIRMED

lp

JAMES V COSTIGAN HEDMAN GIBSON & COSTIGAN 1185 AVENUE OF THE AMERICAS NEW YORK NY 10036